



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 15, 2012, from 8:30 a.m. to 5 p.m. and May 16, 2012 from 8 a.m. to 4 p.m.

Location: Hilton Washington DC/North Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877, 301-977-8900. For those unable to attend in person, the meeting will also be Web cast. The Web cast will be available at the following links.

Blood Products Advisory Committee Web cast link

May 15:

<http://fda.yorkcast.com/webcast/Viewer/?peid=ba104b31fe4c4c099568bacda9a4e5401d>

May 16:

<http://fda.yorkcast.com/webcast/Viewer/?peid=19caf3c8c1624acdaab205ddde9c48581d>

Contact Person: Bryan Emery or Rosanna Harvey, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-1297, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 15, 2012, the committee will discuss as a device panel the evaluation of the safety and effectiveness of the OraQuick In-Home HIV Test. On May 16, 2012, the committee will discuss the evaluation of possible new plasma products frozen following in-process storage at room temperature for up to 24 hours, namely plasma for transfusion prepared from Whole Blood held at room temperature for up to 24 hours prior to separation and freezing, or from apheresis plasma held at room temperature for up to 24 hours before freezing. In the afternoon, the committee will hear update presentations on the following topics: HHS activities related to the evaluation of the donor deferral policy for men who have had sex with other men; a summary of the November 8-9, 2011, public workshop on hemoglobin standards and maintaining an adequate blood supply; and a summary of the November 29, 2011, public workshop on data and data needs to advance risk assessment for emerging infectious diseases for blood and blood products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 8, 2012. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 3:15 p.m. on May 15, 2012, and between approximately 11:30 a.m. and 12:45 p.m. on May 16, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 30, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 1, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bryan Emery, 301-827-1277, or Rosanna Harvey, 301- 827-1297, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 30, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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